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VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

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Issue 100 Contents:

Inequitable Conduct Saga in the US

Post Therasense, in Bristol-Myers Squibb Co. v. Teva Pharma. USA, Inc. (D. Del. Civ. A. No. 10-805-RGA, July 19, 2012), the court denied the patentee's motion for summary judgment against an inequitable conduct defense because the inventor said he had neither written nor read an article in question before it was published raising a credibility concern. "To prove by clear and convincing evidence that a person intended to deceive the PTO twenty years ago, in the absence of any direct evidence that he did so, is about as difficult as climbing Mt. Everest," the Court opined, "I cannot say, however, as a matter of law that it cannot be done. *See Aventis Pharma SA. v. Hospira, Inc.*, 675 F.3d 1324, 1334-37 (Fed. Cir. 2012) (affirming a finding of an inventor's intent to deceive in 1990)."

First-Inventor-to-File Rules

On Thursday, July 26, 2012, the USPTO announces publication in the Federal Register of proposed rules and proposed examination guidelines for the first-inventor-to-file provision of the AIA. The first-

Issue 100	*5114 Kali Era, NandanaYear, Ashadha Month* *2070 Vikramarka Era, NandanaYear, Ashadha Month* *1934 Salivahana Era, Nandana Year, Ashadha Month* *2012 AD, July*

inventor-to-file provision converts the United States from a "first-to-invent" to a "first-inventor-to-file" system. The proposed rules and proposed examination guidelines amend the rules of practice to implement the conversion and set forth the Office's interpretation of how the conversion impacts sections of the Manual of Patent Examining Procedure related to novelty and obviousness. The proposed rules and proposed examination guidelines are accessible here:
First-Inventor-to-File Proposed Rules (77 Fed. Reg. 43742, July 26, 2012
First-Inventor-to-File Proposed Examination Guidelines (77 Fed. Reg. 43759, July 27, 2012)

Publication in the Federal Register of the first-inventor-to-file proposed rules and proposed examination guidelines opens a public comment period running until October 5, 2012.

Also, the USPTO published its final rule to implement the preissuance submissions by third parties provision of the Leahy-Smith America Invents Act (77 Fed. Reg. 42150)

America Innovates Act of 2012 & American Innovation Bank
The bills, H.R. 4720 and S. 2369, are entitled the "America Innovates Act of 2012" were introduced in Congress on April 25th of this year. The bill provides for the U.S. to establish an American Innovation Bank as an independent agency (Sec. 101(a) to promote the commercialization of science and engineering discoveries (Sec. 102(a)) by providing grants, loans, and other assistance to eligible entities and individuals to enable the entities and individuals to perform the necessary research and development to make research discoveries attractive for private investment that will lead to the development of new companies, products, and jobs. Sec. 102(b). There are provisions for a Board (Sec. 101(b)(1)) and a Director, appointed by the President with the advice and consent of the Senate (Sec. 101(B)(2)); the Board will advise the Director on new and emerging areas of research and industry that would benefit from investment from the Bank (Sec. 101(b)(3)(A)) and critically evaluate the success of the Bank's investments in helping to commercialize scientific discoveries and create new companies and jobs. (Sec. 101(B)(3)(B)) The bill also provides for annual Reports of its activities to Congress (Sec. 103(a)) that will include at a minimum the number of patents, products, new companies and jobs resulting from Bank investments (Sec. 103(b)).

Grants will be available to eligible entities (Sec. 104(a)) including institutes of higher education as defined by section 101 of the Higher Education Act of 1965 (20 USC 101), Sec. 104(B)(1) and nonprofit

research institutions that focus on science research (Sec. 104(B)(2)) such as life sciences, medicine, computer sciences, communications, technology, physical sciences, engineering and o]ther research areas determined important for economic development by the Director. (Sec. 104(d)(1) – (4)) The Bank is intended to help companies navigate the "valley of death" where university-related start-up companies go through initial funding before having sufficient experimental results to attract venture capital or large company investment or commercialize their products.
http://www.gpo.gov/fdsys/pkg/BILLS-112hr4720ih/pdf/BILLS-112hr4720ih.pdf
http://www.gpo.gov/fdsys/pkg/BILLS-112s2369is/pdf/BILLS-112s2369is.pdf

Big Pharma
AstraZeneca recently announced it would pay $3.4 billion to Amylin Pharmaceuticals - after another company, Bristol-Myers Squibb, acquires Amylin in a $7 billion deal. AstraZeneca will be sharing expenses and profits from Amylin's diabetes drugs, with Bristol-Myers Squibb. Meanwhile, GlaxoSmithKline said it is continuing its now-contentious quest to take over Human Genome Sciences, which is based in Rockville, Md. In April, GSK said it was making an offer of $13 per share for HGS, in other words, $2.6 billion. HGS management and board members were not receptive. They claim that the offer undervalues the company and that it plans to seek other offers.
http://www.philly.com/philly/blogs/phillypharma/161054305.html

GlaxoSmithKline has reached an agreement with the US Government, multiple states and the District of Columbia to conclude the company's three most significant ongoing Federal government investigations. The final settlement is a result of negotiations that reached agreement in principle in November 2011. GSK will make payments totaling $3 billion that are covered by existing provisions and will be funded through existing cash resources. The agreement resolves liabilities related to: an investigation begun by the US Attorney's office of Colorado in 2004 and, later, Massachusetts into GSK's sales and marketing practices for nine products. The other two investigations were the U.S. Department of Justice's. They were an investigation of possible inappropriate use of the nominal price exception under the Medicaid

Rebate Program and an investigation of the marketing and regulatory submissions of Avandia. http://www.biospace.com/News/glaxosmithkline-settles-healthcare-fraud-case-for/265658

A jury in New Jersey returned an $18 million verdict to two former Accutane users against Nutley, N.J.-based pharmaceutical companies Hoffmann La-Roche Inc. and Roche Laboratories, subsidiaries of Roche Holding AG. The plaintiffs took Accutane for treatment of their acne and developed ulcerative colitis--a debilitating, permanent disease--as a result. Each was awarded $9 million in compensatory damages for the injuries caused by their use of Accutane. http://www.biospace.com/News/roche-ordered-to-pay-18-million-to-former-accutane/265556

The European Medicines Agency said it was investigating Swiss group Roche Holding AG after a routine inspection found it had failed to properly assess 80,000 cases of possible drug side effects. The issue relates to medicines that were part of a financial reimbursement system in the United States. Roche is the world's largest maker of cancer medications, drugs for viral infections, drugs for central nervous system disorders and for inflammatory diseases. http://www.foxnews.com/health/2012/06/22/drug-company-roche-accused-improperly-reporting-drug-side-effects/

Yoga is not Copyrightable

Yoga poses and sequences of poses are exercises and not subject to copyright law protection, announced the United States Copyright Office recently. "Exercise is not a category of authorship in section 102 and thus a compilation of exercises would not be copyrightable subject matter," according to the Office's statement of policy. The policy made clear that the selection and arrangement of otherwise uncopyrightable matter is not subject to copyright protection.

Under Section 102 of the Copyright Act, 17 U.S.C. § 102(a), works of authorship that can be protected by copyright law are limited to:
(1) literary works;
(2) musical works, including any accompanying words;
(3) dramatic works, including any accompanying music;
(4) pantomimes and choreographic works;
(5) pictorial, graphic, and sculptural works;
(6) motion pictures and other audiovisual works;

(7) sound recordings; and
(8) architectural works.

Section 102 also prohibits copyright protection for compilations that amount "to any idea, procedure, process, system, method of operation, concept, principle or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work." 17 U.S.C. § 102(b). The policy explains, "…. while such a functional system or process may be aesthetically appealing, it is nevertheless uncopyrightable subject matter. A film or description of such an exercise routine or simple dance routine may be copyrightable, as may a compilation of photographs of such movements. However, such a copyright will not extend to the movements themselves, either individually or in combination, but only to the expressive description, depiction, or illustration of the routine that falls within a section 102(a) category of authorship."
https://www.federalregister.gov/articles/2012/06/22/2012-15235/registration-of-claims-to-copyright#p-3

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Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih!
(Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

Issue 100	*5114 Kali Era, Nandana Year, Ashadha Month* *2070 Vikramarka Era, Nandana Year, Ashadha Month* *1934 Salivahana Era, Nandana Year, Ashadha Month* *2012 AD, July*